

## § 417.126

## 42 CFR Ch. IV (10–1–99 Edition)

(1) In the case of hospitals, are either accredited by the Joint Commission on Accreditation of Health Care Organizations, or certified by Medicare.

(2) In the case of laboratories, are either CLIA-exempt, or have in effect a valid certificate of one of the following types, issued by HCFA in accordance with section 353 of the PHS Act and part 493 of this chapter:

- (i) Registration certificate.
- (ii) Certificate.
- (iii) Certificate of waiver.
- (iv) Certificate of accreditation.

(3) In the case of other affiliated institutional providers, are certified for participation in Medicare and Medicaid in accordance with part 405, 416, 418, 488, or 491 of this chapter, as appropriate.

[58 FR 38068, July 15, 1993, as amended at 59 FR 49843, Sept. 30, 1994]

### § 417.126 Recordkeeping and reporting requirements.

(a) *General reporting and disclosure requirements.* Each HMO must have an effective procedure to develop, compile, evaluate, and report to HCFA, to its enrollees, and to the general public, at the times and in the manner that HCFA requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the following:

- (1) The cost of its operations.
- (2) The patterns of utilization of its services.
- (3) The availability, accessibility, and acceptability of its services.
- (4) To the extent practical, developments in the health status of its enrollees.
- (5) Information demonstrating that the HMO has a fiscally sound operation.
- (6) Other matters that HCFA may require.

(b) *Significant business transactions.* Each HMO must report to HCFA annually, within 120 days of the end of its fiscal year (unless for good cause shown, HCFA authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in paragraph (c) of this section) between the HMO and a party in interest.

(2) With respect to those transactions—

(i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(3) A combined financial statement for the HMO and a party in interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the HMO go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the HMO.

(c) *“Significant business transaction” defined.* As used in paragraph (b) of this section—

(1) Business transaction means any of the following kinds of transactions:

- (i) Sale, exchange or lease of property.
- (ii) Loan of money or extension of credit.
- (iii) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(A) Salaries paid to employees for services performed in the normal course of their employment; or

(B) Health services furnished to the HMO's enrollees by hospitals and other providers, and by HMO staff, medical groups, or IPAs, or by any combination of those entities.

(2) *Significant business transaction* means any business transaction or series of transactions of the kind specified in paragraph (c)(1) of this section that, during any fiscal year of the HMO, have a total value that exceeds \$25,000 or 5 percent of the HMO's total operating expenses, whichever is less.

(d) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the HMO and each of these parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(4) Upon written request from an HMO showing good cause, HCFA may waive the requirement that its combined financial statement include the financial information required in this paragraph (d) with respect to a particular entity.

(e) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an HMO in its offerings, the HMO must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular HMO) under the Employee Retirement Income Security Act of 1974 (ERISA).

(i) The HMO must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA.

(ii) Loan of money or extension of credit.

(iii) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(A) Salaries paid to employees for services performed in the normal course of their employment; or

(B) Health services furnished to the HMO's enrollees by hospitals and other providers, and by HMO staff, medical groups, or IPAs, or by any combination of those entities.

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(2) The HMO must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA.

#### Subpart D—Application for Federal Qualification

##### § 417.140 Scope.

This subpart sets forth—

(a) The requirements for—

(1) Entities that seek qualification as HMOs under title XIII of the PHS Act; and

(2) HMOs that seek—

(i) Qualification for their regional components; or

(ii) Expansion of their service areas;

(b) The procedures that HCFA follows to make determinations; and

(c) Other related provisions, including application fees.

[59 FR 49836, Sept. 30, 1994]

##### § 417.142 Requirements for qualification.

(a) *General rules.* (1) An entity seeking qualification as an HMO must meet the requirements and provide the assurances specified in paragraphs (b) through (f) of this section, as appropriate.